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K031428

3.0 510(k) Summary

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- Sponsor:** Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700
- Device Name:** Synthes Large External Fixation Clamps – MR Safe:
- Synthes Multi-Pin Clamps, (four and six position) – MR Safe
 - Synthes Rod Attachment for the Multi-Pin Clamp – MR Safe
 - Synthes Tube-to-Tube Clamp – MR Safe
 - Synthes Open Adjustable Clamp – MR Safe
- Classification:** Class II, 21 CFR §888.3030 – Single/multiple component bone fixation appliances and accessories.
- Predicate Devices:** Synthes Large External Fixation Clamps:
- Synthes Universal Clamp, (four and six position), and Rod Attachment
 - Synthes Tube-to-Tube Clamp
 - Synthes Adjustable Clamp
- Device Description:** Synthes MR Safe Large External Fixation Clamps are components of an external fixation frame that form a construct intended to treat long bone and pelvic fractures. They are all made from non-magnetic materials and are intended for use in the MR environment. Frame components for these MR Safe devices are designed for use with Synthes Ø11.0 mm carbon fiber rods and Synthes Schanz screws in diameters of 4.0 – 6.0 mm.
- Intended Use:** Synthes Large External Fixation Clamps – MR Safe are indicated for use in construction of an external fixation frame for treatment of long bone and pelvic fractures that require external fixation. Specifically, the Synthes MR Safe Large External Fixation Clamps and their accessories are intended for:
- Stabilization of open or closed fractures with soft tissue injuries;
 - Polytrauma;
 - Vertically stable pelvic fractures or as a treatment adjunct for vertically unstable pelvic fractures;
 - Arthrodesis and osteotomies with soft tissue problems;
 - Failures of total joints;
 - Neutralization of fractures stabilized with limited internal fixation;
 - Non-unions/septic non-unions;
 - Intraoperative reduction/stabilization tool to assist with indirect reduction;
 - Unilateral rectilinear bone segment transport or leg lengthening.
- Material:** Stainless steel, titanium alloy and cobalt alloy



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Bonnie J. Smith
Senior Regulatory Affairs Associate
Synthes (USA)
1690 Russell Road
Paoli, PA 19301

Re: K031428

Trade/Device Name: Synthes Large External Fixation Clamps – Magnetic Resonance Safe
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component bone fixation appliances and accessories
Regulatory Class: II
Product Code: LXT
Dated: April 30, 2003
Received: May 12, 2003

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost
for

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use Statement

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510(k) Number (if known): K031428

Device Name: Synthes (USA) Large External Fixation Clamps – MR Safe

INDICATIONS:

Synthes Large External Fixation Clamps – MR Safe are indicated for use in construction of an external fixation frame for treatment of long bone and pelvic fractures that require external fixation. Specifically, the Synthes MR Safe Large External Fixation Clamps and their accessories are intended for:

- Stabilization of open or closed fractures with soft tissue injuries;
- Polytrauma;
- Vertically stable pelvic fractures or as a treatment adjunct for vertically unstable pelvic fractures;
- Arthrodesis and osteotomies with soft tissue problems;
- Failures of total joints;
- Neutralization of fractures stabilized with limited internal fixation;
- Non-unions/septic non-unions;
- Intraoperative reduction/stabilization tool to assist with indirect reduction;
- Unilateral rectilinear bone segment transport or leg lengthening

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031428